**IN THE UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF TEXAS**
**Waco Division**

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| CHILDREN'S HEALTH DEFENSE, *et al.* | ) | |
| | ) | |
| Plaintiffs, | ) | |
| | ) | Case No. 6:22-cv-00093 |
| v. | ) | |
| | ) | |
| FOOD and DRUG ADMINISTRATION, *et al.*, | ) | |
| | ) | |
| Defendants. | ) | |
| _____ | ) | |

**PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS AMENDED COMPLAINT**

**TO THE HONORABLE JUDGE OF THE COURT:**

Plaintiffs Children's Health Defense ("CHD"), Deborah L. Else, Sacha Dietrich, Aimee Villella McBride, Jonathan Shour, and Rebecca Shour (hereinafter collectively "Plaintiffs"), file this opposition to Defendants U.S. Food and Drug Administration's ("FDA") and Robert M. Califf's, (hereinafter collectively "Defendants') Motion to Dismiss the First Amended Complaint [ECF No. 26] for Lack of Subject-Matter Jurisdiction and Failure to State a Claim ("MTD") [ECF No. 29].

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## INTRODUCTION

The FDA claims it is above the law and denies any remedy to those aged 6 months to eleven years, from its arbitrary and capricious authorization of COVID -19 injections, including those in foster care. The Constitution embraces judicial review of this extraordinarily consequential agency action as a cognizable case or controversy. Indeed, for the Constitution's tripartite system of checks and balances to function, this court has the precise power it needs to recognize Plaintiffs' injuries that have arisen from inadequate agency review and decision making, and subsequent false advertising of COVID-19 shots. The injuries Plaintiffs suffer include their inability to rely on FDA marketing any longer; resultant health uncertainty for their children; risk of involuntary childhood injection of dangerous biologics; and enormous costs to CHD to correct FDA's misinformation. This case or controversy urgently demands judicial oversight.

FDA claims immunity from suit on grounds everything it did was an "emergency power." The problem with that argument is four-fold: first, falsely claiming an emergency exists for young children from COVID-19 is itself challenged in this suit; second, falsely claiming a drug is safe for little children is not an emergency power; third, falsely claiming a drug is effective for little children is not an emergency power; and fourth, redefining the word vaccine itself to relabel a drug that is not a vaccine a "vaccine" is not an emergency power. All such agency actions are subject to judicial review. The FDA's marketing of this drug is not an emergency use authorization power even if they disguise it all under their "emergency use authorization." This case is about the misuse and misappropriation of emergency powers to market an unsafe, dangerous drug to little kids to deny them informed consent. CHD and parent Plaintiffs suffer ongoing injury from the mismarketing of this drug to little kids. The Constitution intended courts

to address precisely this kind of "case or controversy". The FDA's motion to dismiss at this pleading stage should be denied. The least protected, most vulnerable lives depend upon it.

## STANDARD OF REVIEW

Without discovery or trial, the FDA seeks to dismiss this case of extraordinary public importance. Yet to do so, the FDA must show that no facts exist, whether alleged, possibly alleged in an amendment, or discoverable, that provide a basis for any claim or cause of action. The FDA cannot do this. "Even if it seems 'almost a certainty to the court that the facts alleged cannot be proved to support the legal claim,' the claim may not be dismissed so long as the complaint states a claim." *Clark v. Amoco Prod. Co.,* 794 F.2d 967, 970 (5th Cir. 1986) (quoting *Boudeloche v. Grow Chem. Coatings Corp.,* 728 F.2d 759, 762 (5th Cir. 1984); *see also U.S. ex rel. Riley v. St. Luke's Episcopal Hosp.* 355 F.3d 370, 376 (5th Cir. 2004). "A claim will not be dismissed on a Rule 12(b)(6) motion unless it appears to a certainty that no relief can be granted under any set of facts provable in support of its allegations". *Lowe v. Hearst Commc'ns, Inc.*, 414 F. Supp. 2d 669 (W.D. Tex. 2006), *aff'd,* 487 F.3d 246, fn. 1 (5th Cir. 2007).

"Federal Rule of Civil Procedure 8(a)(2) requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 555 (2007) (citing *Conley v. Gibson,* 355 U.S. 41, 47 (1958)). Critically, at all times at this pleading stage of the case, the Court must accept as true all inferences, assumptions and facts of Plaintiffs' complaint, including what amendments could provide and what discovery could show, against the FDA. *Jenkins v. McKeithen,* 395 U.S. 411, 421-422 (1969). "In passing on a motion to dismiss . . . for failure to state a cause of action, the allegations of the complaint should

be construed favorably to the pleader. ” *Scheuer v. Rhodes,* 416 U.S. 232, 236, 94 S. Ct. 1683, 40 L. Ed. 2d 90 (1974); *see also Bustos v. Martini Club, Inc.,* 599 F.3d 458, 461 (5th Cir. 2010).

## ARGUMENT

The FDA mislabeled a dangerous biologic to toddlers and children as safe, effective, and a vaccine, when it is neither safe, effective, nor a vaccine. The FDA achieved this by ignoring the CHD's Citizen Petition, skipping any participatory process such as notice-and-comment, colluding with social media platforms to censor and silence CHD, and using children's icons like Big Bird and Elmo to market the product as a safe and effective vaccine, necessary in an emergency when no emergency for children even existed, and when the product poses more risk than benefit to children.

The FDA's actions caused CHD to undergo a complete revamping of its budgeted plans, reverse course entirely on its public educational focus, conduct massively detailed inquiries to do the job the FDA failed to do, incur unprecedented expense to educate the public on the risks the FDA failed to inform them of, discover completely new means of communication with the public, and seek new funds for this extraordinary expense the FDA caused. CHD member parents face complete collapse of confidence in the FDA, a dramatic surge in uncertainty for their children, and daily risk of involuntary childhood injections.

The FDA is not above the law, the courts, the Constitution, or the citizens whom its actions may injure. The FDA denies Plaintiffs informed consent –a right the world once considered so universal and sacred, as a *jus cogens* norm, that the U.S. ordered the execution of those who violated it in Nuremberg, Germany in 1947. The FDA cannot be allowed to operate with no accountability for its role in causing vaccine injury to the most vulnerable amongst us – young children, too often without parental protection. The FDA asks this court to declare itself

powerless and the constitutional check on executive power mute. That is not the law, and this Court should say so.

## IV. THIS CASE CREATES A CONSTITUTIONALLY COGNIZABLE CASE OR CONTROVERSY: PLAINTIFFS HAVE ARTICLE III STANDING

### A. Legal Standard: Organizational Standing

The Constitution empowers the judicial branch power to adjudicate any "case or controversy." *Article III § 2 of the United States Constitution*. The Court construes this to apply whenever any plaintiff has any "personal interest at the commencement of the litigation." *Barry v. Lyon*, 834 F.3d 706 (2016); see *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). At the pleading stage, courts must presume the complaint's "general allegations embrace those specific facts that are necessary to support the claim." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (citing *Lujan v. National Wildlife Federation*, 497 U.S. 871, 889 (1990)). "The presence of one party with standing is sufficient to satisfy Article III's case-or-controversy requirement." *Rumsfeld v. Forum for Academic & Institutional Rights, Inc.*, 547 U.S. 47, 53, n2 (2006).

As an organization, CHD can demonstrate standing in two ways: (1) organizational standing ("an organization may have standing on its own behalf"); and (2) associational standing ("the organization can assert representational standing on behalf of its members"). *Patterson v. Rawlings*, 287 F. Supp. 3d 632 (N.D. Tex. 2018). CHD satisfies both to establish an injury-in-fact and bring this suit. *See e.g.*, 5 U.S.C. § 701-706; *Bank of Am. Corp. v. City of Miami, Fla.*, 137 S. Ct. 1296, 1303 (2017); *Summers*, 555 U.S. at 494; *see also OCA-Greater Houston v. Texas*, 867 F.3d 604, 610 (5th Cir. 2017). Organizations enjoy standing whenever agency action causes a "consequent drain on the organization's resources" originally budgeted toward other

items to "counteract defendant's alleged unlawful practices." See *Association of Community Orgs. For Reform Now v. Fowler,* 178 F.3d 350, 360 (5th Cir. 1999).

The Supreme Court held that an organization's pleading sufficiently meets Article III standing where it alleges that a "concrete and demonstrable injury to the organization's activities – with the consequent drain on the organization's resources." *Havens Realty Corp. v. Coleman,* 455 U.S. 363, 378 (1982). "Ultimately, to establish standing in its own right, an organization must allege facts to show that it devoted resources to counteract defendant's alleged unlawful practices." *Advocacy Ctr. V. La. Tech Univ*., 2019 U.S. Dist. Lexis 47726 *8 (quoting *Association of Community Orgs. For Reform Now v. Fowler*, 178 F.3d 350, 360 (5th Cir. 1999).

Decisions of sister Circuit Courts affirm this same principle of an organization's standing under Article III, where its pre-litigation efforts to evaluate and challenge government acts result in a drain on the organization's resources. *See e.g., Abigail Alliance for Better Access to Developmental Drugs v. Eschenback,* 469 F.3d 129 (D.C. Cir. 2006); *Hooker v. Weathers*, 990 F.2d 913, 915 (6th Cir. 1993) ("Hooker"); *El Rescate Legal Services, Inc. v. Executive Office of Immigration Review*, 959 F.2d 742, 748 (9th Cir. 1991) ("El Rescate"); *Public Citizen v. Foreman,* 631 F.2d 969, fn. 12 (D.C.Cir.1980); *Natural Resources Defense Council, Inc. v. SEC,* 606 F.2d 1031 (D.C.Cir.1979); *Am. Acad. of Pediatrics v. FDA,* 379 F. Supp. 3d 461 (D. Md. 2019).

In *El Rescate,* the Ninth Circuit held: "The allegation that the [defendant government agency]'s policy frustrates these goals and requires the organizations to expend resources in representing clients they otherwise would spend in other ways is enough to establish standing." (citing *Havens Realty, supra,* 455 U.S. at 379.) Equally, in *Hooker,* the Sixth Circuit found standing when agency actions forced an organizational plaintiff to devote resources to

investigating what the agency failed to, then standing to sue existed. *Ibid*. Furthermore, the DC Circuit Court in *Natural Resources Defense Council, Inc. v. SEC,* 606 F.2d 1031 (D.C.Cir.1979) found that "organizations dedicated to inducing more responsive attitudes among American corporations towards the problems of environmental degradation and inequality of employment opportunity" also enjoyed standing to contest the failure of the SEC "to promulgate rules requiring comprehensive disclosures by corporations of their environmental and equal employment policies" because the plaintiff's "interest was judicially cognizable, personal to them, and was arguably impaired" by defendants' actions. 606 F.2d at 1036.

An organization need not show an "overly burdensome" injury to satisfy standing. *Public Citizen v. Foreman,* 631 F.2d 969, fn. 12 (D.C.Cir.1980) ("*Public Citizen*"). In *Public Citizen,* the court held that a nonprofit public interest group and two of its members had standing against the government to seek a declaratory judgment that nitrates used in curing bacon are an "unsafe" food additive under the Federal Food, Drug, and Cosmetic Act ("FDCA"). The Court found that because nitrite-free bacon "was not readily available at a reasonable price", plaintiffs sustained an injury, even though they could abstain from eating bacon or purchase the more expensive nitrite-free bacon and the injury was not "overly burdensome." *Id.* at fn. 12; *see also Pac. Legal Found. v. Goyan,* 500 F. Supp. 770 (D. Md. 1980), rev'd, 664 F.2d 1221 (4th Cir. 1981) ("an 'identifiable trifle' can be enough for standing").

Finally, where a plaintiff sufficiently alleges actual injury to itself under certain federal statutes, the plaintiff is permitted to prove that the rights of others were also infringed and to seek relief on their behalf as well. Thus, in *Gladstone, supra,* 441 U.S. at 103, a municipality sued a real estate broker for violating the Civil Rights Act by steering prospective home buyers to different residential areas according to race. Because the city itself claimed actual injury (loss of

racial balance and stability), it had standing to prove that the rights of others (prospective home buyers) were also infringed. *See also Virginia v. American Booksellers Ass'n, Inc*., 484 U.S. 383, 392-393 (1988). This equally applies in statutory enforcement of the Administrative Procedures Act and to those aggrieved by agency action related thereto. *See 5 U.S.C. § 702*.

### B. Plaintiff CHD Presents a Case or Controversy: Organizational Standing

The FDA mislabeled and falsely marketed a biologic for mass consumption by young children without real opportunity for their parents or guardians to give informed consent. CHD objected throughout the process, including through a Citizen Petition, but the FDA ignored CHD's objections. Now, reports arise each day of injured children. FDA's refusal to meaningfully address the Citizen Petition and amendments thereto, compounded by FDA's collusion to censor CHD on precisely these issues on social media platforms, paved the path for FDA's mass deception on the safety, efficacy, and nature of this product. FDA's actions caused CHD a "consequent drain on the organization's resources" to "counteract defendant's alleged unlawful practices." See *Association of Community Orgs. For Reform Now v. Fowler*, 178 F.3d 350, 360 (5th Cir. 1999). Such resource diversion, by itself, creates a Constitutionally cognizable case or controversy. *Bank of Am. Corp. v. City of Miami, Fla.*, 137 S. Ct. 1296, 1303 (2017). As a fellow federal court noted: "the FDA appears to be simply wrapping itself in the flag of law enforcement discretion to justify its authority and masquerade an otherwise seemingly callous indifference to the health consequences of those imminently facing" the harm. *Beaty v. Food & Drug Admin.*, 853 F.Supp.2d 30 (D.D.C. 2012).

When the risk of a drug or biologic is only possible due to FDA's actions, then that risk constitutes a clearly cognizable Constitutional case or controversy for those affected. *Beaty v. Food & Drug Admin.*, 853 F.Supp.2d 30 (D.D.C. 2012). Indeed, fellow federal courts found

jurisdiction over an analogous suit concerning the same kind of organizational plaintiff and the same defendant. *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461 (D. Md. 2019). A group dedicated to educating people on public health issues incurred more costs in educating the public about health risks than they would have had the FDA done its job correctly. *Id*. Equally, fellow federal courts found that an organization akin to CHD pleaded plausible injury when the FDA's actions impacted its advocacy, educational activities and the cost related thereto. *Abigail Alliance for Better Access to Developmental Drugs v. Eschenback*, 469 F.3d 129 (D.C. Cir. 2006).

FDA's mislabeling and mismarketing of these COVID injections injured CHD in the expenditure of resources necessary to "eliminate harmful exposures, hold those responsible accountable, and to establish safeguards to prevent future harm" to children.[1] FDA directly targeted CHD by not only failing to address, but acting in direct contradiction to, CHD's Citizen Petition. Am. Compl. ¶ 148. This follows a pattern of Defendants and others in government targeting CHD for adverse actions, by demanding major social media platforms prevent it from reaching the public[2] and precluding it from raising funds online for its organizational efforts. In anticipation of the Emergency Use Authorization ("EUA") for children ages 6 months through 5 years, CHD again sent a letter to the FDA on June 10, 2022 outlining why the EUA was illicit agency action. Am. Compl. ¶ 152. Yet, the FDA did not pause, delay, or even reply to the letter. Defendants continuously denied CHD its procedural remedies under the Administrative Procedures Act ("APA") and a satisfactory answer to its concerns.

[1] Children's Health Defense Mission Statement, available at http://childrenshealthdefense.org.
[2] In fact, on August 17, 2022, CHD was censored and deplatformed without warning from Facebook and Instagram. Both accounts, which had amassed hundreds of thousands of followers, were permanently deactivated. *See* https://childrenshealthdefense.salsalabs.org/chd-censorship-attack.

Point in fact, FDA's activities created several roles that CHD was forced to fill: (1) CHD devoted resources over the past 18 months to investigating the FDA's actions, including its involvement in safety and efficacy studies, clinical trial oversight, interpretation of data, misrepresentation of data, rationale for authorization and approval of COVID-19 related biologics, abuse of emergency powers, and public statements and advertising of such biologics; (2) CHD worked with its members to address coercion and pressure to vaccinate, as well as discrimination that members and their families face. CHD has numerous members and employees whose children fall within the age cohorts that the FDA now authorizes to receive the Moderna and Pfizer-BioNTech vaccines; (3) CHD worked through its newsletters, online video news platforms, and live commentary to educate the public with real information necessary to satisfy *informed* consent and combat the misinformation that the FDA and CDC continue to promote.

The APA creates judicially enforceable private interests in efficacious governance that protects the democratic guardianship of our Constitutional republic. The APA expressly authorizes standing for those injured by agency action: "a person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. Indeed, the entire purpose of the APA is to assure judicial review of agency action, specifically authorizing federal courts to "hold unlawful and set aside agency action findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority or limitations." 5 U.S.C. § 706(2)(A), (C).

Finally, CHD has standing as the organization seeks relief on behalf of classes of children who likely will experience injury due to FDA's EUAs. In particular, CHD seeks to protect

children between the ages of 6 months and 11 years of age under Texas state conservatorship who are not protected by a parent or guardian, who are being allowed to "consent" to a potentially dangerous medical procedure under state pressure, without the maturity to be able to appropriately weigh the risks and benefits. Am. Compl. ¶ 97-111; CHD, in alignment with its mission, represents these children who are subject to imminent threat of injury from these injections without parental consent in the Waco-McClennan area. Am. Compl. ¶ 113.

### C. Plaintiff CHD Presents a Case or Controversy: Associational Standing

Plaintiff CHD's associational standing also establishes a Constitutionally cognizable case or controversy. "An organization has standing to bring suit on behalf of its members when: (1) its members would otherwise have standing to sue in their own right; (2) the interests it seeks to protect are germane to the organization's purpose; and (3) neither the claim asserted nor the relief requested requires the participation of individual members." *Texans United for a Safe Econ. Educ. Fund v. Crown Cent. Petroleum Corp.*, 207 F.3d 789, 792 (5th Cir. 2000); *Friends of the Earth, Inc. v. Chevron Chem. Co.*, 129 F.3d 826, 827–28 (5th Cir. 1997)).

#### i. CHD Members Interests Create a Constitutionally Cognizable Case or Controversy: Associational Standing

CHD's allegations satisfy associational standing because, as detailed supra, Deborah L. Else, Sacha Dietrich, Aimee Villella McBride, Jonathan Shour, and Rebecca Shour, all members of CHD, have been injured by FDA's action and have individual standing. Thus, CHD has associational standing to bring suit on their behalf.

#### ii. CHD Aims to Protect Interests Germane to Its Purpose

Defendants do not contest that CHD satisfies the other two criteria for associational standing. While CHD boasts members in the tens of thousands, CHD reaches millions every month through publications, its TV channel and social media. CHD's mission is to "end

childhood health epidemics by working aggressively to eliminate harmful exposures, hold those responsible accountable, and to establish safeguards to prevent future harm."[3] The organization's purpose seeks to address "public health policies and practices that are harming our children" and "call[s] for more research and transparency."[4] These goals pertain not only to actions that directly affect children, but also to those that will set long-lasting and dangerous precedents that will affect future generations. CHD is the voice for those oppressed by corporate capture of federal agencies, as is the case here.

#### iii. The Relief CHD Seeks Does Not Require Individual Member Participation

Finally, CHD's claims do not require individual members to participate directly in the suit, and thus the third factor of associational standing is satisfied. In *Associated Contractors of America v. Metropolitan Water Dist. Of S. Cal.,* 159 F.3d 1178, 1181 (9th Cir. 1998), the court held that the individual participation of an association of contractors was not required to assert standing where declaratory and injunctive relief were sought rather than monetary damages, and thus individualized proof was not necessary to the resolution of the action. Similarly, Plaintiffs' Amended Complaint contains no prayer for monetary damages, only for the court to stay and vacate the FDA's authorizations and misleading promotion of the COVID vaccines. Am. Compl. Prayer for Relief. As such, individual members' participation is not required.

### D. Plaintiffs Deborah L. Else, Sacha Dietrich, Aimee Villella McBride, Jonathan Shour, and Rebecca Shour Satisfy Article III Standing as Individuals

"To satisfy Article III's standing requirements, a plaintiff must show (1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not

[3] https://childrenshealthdefense.org
[4] *Id.*

conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181, 120 S. Ct. 693, 145 L.Ed. 2d 610 (2000) (quoting *Lujan*, 504 U.S. at 560-561). "It can scarcely be doubted that for a plaintiff who is injured or faces the threat of future injury due to illegal conduct ongoing at the time of suit, a sanction that effectively abates that conduct and prevents its recurrence provides a form of redress." *Laidlaw*, 528 U.S. at 185-86.

Exposure to potentially harmful products constitutes a remedial injury for a Constitutionally cognizable case or controversy. *Baur v. Veneman*, 352 F.3d 625 (2d Cir. 2003); *see also Ctr. for Food Safety v. Price*, No. 17-CV-3833 (VSB), 2018 WL 4356730, *6 (S.D.N.Y. Sept. 12, 2018). Agency actions that increase health-related uncertainty constitute a remediable injury for a Constitutionally cognizable case or controversy. *New York Public Interest Research Group v. Whitman*, 321 F.3d 316 (2d Cir. 2003). Impairing a parent's medical control over her children's care has previously been found to constitute a Constitutionally cognizable case or controversy. *Tummino v. Torti*, 603 F.Supp.2d 519 (E.D.N.Y. 2009).

Furthermore, federal courts specifically allow consumers to bring suit against the FDA when the agency has "increased the risk that they will purchase and consume unsafe or ineffective drugs." *Cutler v. Kennedy*, 475 F.Supp. 838, 848 (D.D.C.1979). Noting that the focus of the standing inquiry is on the "fact, and not the amount or severity, of the injury," the court held that:

> [I]f, as the plaintiffs contend on the merits, the FDA is authorizing drugs to be marketed in violation of the [FDCA], it has increased the risk that plaintiffs will be exposed to unsafe or ineffective drugs by depriving them of regulatory protection which the statute accords all drug consumers. This risk and deprivation itself constitutes a distinct and palpable injury to plaintiffs' statutory interests as drug consumers.

475 F.Supp. at 848-849; *see also United States v. SCRAP*, 412 U.S. 669, 688-89 & n.14, 93 S.Ct. 2405, 37 L.Ed.2d 254 (1973); *see also Animal Legal Def. Fund v. Azar*, No. 20-CV-03703-RS, 2021 WL 4477901, *3 (N.D. Cal. Feb. 23, 2021).

Plaintiffs have shown that they have suffered an injury in fact that is (a) concrete and particularized, and (b) actual or imminent, the injury being fairly traceable to the FDA's actions, which satisfies Article III's case-or-controversy requirement. *Lujan* 504 U.S. at 560-561. All individual parent Plaintiffs have children who are directly threatened by FDA's authorizations and the false advertising of them. FDA's misrepresentations have led to continuous coercion, propaganda, and advertisements aimed directly at children, to which Plaintiffs' children are subjected daily. Plaintiffs' children are bombarded with messaging encouraging them to take an improperly authorized vaccine via advertisements on television, radio shows, announcements, and signage in stores and even promotion in children's television programming. Plaintiff Deborah Else attests to enduring vaccine propaganda from school administrators and pediatricians aimed at her children. Am. Compl. ¶ 128; Else Decl., ECF No. 14-1. Plaintiff Sacha Dietrich further asserts that her children experience constant harassment from directives and pressure to receive the COVID-19 biologic from the media and other children. Am. Compl. ¶ 53; Dietrich Decl., ECF No 14-1.

Plaintiffs' children face the looming threat of being pushed out of society as the culture of mass vaccination and medical mandates, now directed at children as young as 6 months, continues as a result of FDA's actions.[5] Their children also face the risk of expanding vaccine mandates, including those preventing them from receiving life-saving transplants and medical

[5] Most recently, Washington D.C. mandated that all students attending public or private schools be fully vaccinated for COVID-19 for the 2022-2023 school year.

treatment. Am. Compl. ¶ 33. Defendants note that Texas Governor Greg Abbott has signed an executive order prohibiting vaccine mandates. MTD, p. 8. However, such an executive order has not prevented discriminatory and cruel treatment towards the unvaccinated –particularly children—which, as Defendants admit, is in direct violation of the assurance included in the EUA statute that a decision to not take the COVID-19 vaccine "will not change [the] child's standard medical care." MTD, p. 3; *see* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III).

The threat of being denied life-saving treatment is not the remote risk Defendants would have this Court believe. MTD, p. 7. No child is immune from the danger of an accidental injury or emergency medical condition. Defendants hope to evade responsibility by claiming that because Plaintiffs' children have not required life-saving treatment, Defendants do not put them at risk. Furthermore, Defendants would have the Court believe that coercive pressures, false advertising, and propaganda aimed at young children to take a dangerous, experimental, mRNA gene therapy do not alone present an injury. In fact, however, they do.

Specifically, Plaintiffs Jonathan and Rebecca Shour are at risk from mandates around the country. As a member of the Navy, Chaplain Shour and his family relocate around the country without any say in their residence. Am. Compl. ¶ 130. At any time, Chaplain Shour could be stationed in a state that implements strict mandates and, as a result, his children could face discrimination and being ostracized from certain activities because of vaccination status. The Shours have already been ostracized due to their religious objections to the COVID-19 vaccine.

In addition, Texas law puts Plaintiffs' children at risk from being injected with this vaccine against parents' wishes. Texas law, Am. Compl. Fn. 54, permits adults other than a child's parents or guardian to consent to the child being vaccinated. While parents are intended to be the decision-makers for their children's health, when an over-zealous family member,

friend, or childcare provider can consent to potentially dangerous medical treatment, Plaintiffs are at risk of having their child unwillingly vaccinated. (Waco County's consent form requires only an unspecified adult's signature for vaccination.) Plaintiffs, who have rightfully and conclusively decided that it is not in the best interest of their child to be vaccinated against COVID-19 have the palpable fear that their child may be vaccinated without their consent. Even if Plaintiffs' children are not yet subject to mandates or faced with the necessity for life-saving treatment, they face constant threat of another adult consenting to their vaccination in Texas.

Plaintiffs also have standing on the grounds that they are no longer able to rely on FDA representations now or in the future. The Ninth Circuit has held that there are scenarios in which the threat of future harm could be sufficient for standing, including the "consumer's plausible allegations that she will be unable to rely on the product's advertising or labeling in the future, and so will not purchase the product although she would like to." *Davidson v. Kimberley-Clark Corporation,* 873 F.3d 1103 (9th Cir. 2017) ("Davidson I"). This was affirmed in *Davidson v. Kimberly-Clark Corporation,* No. 15-16173, 2018 U.S. App. LEXIS 12204 (9th Cir. May 9, 2018) ("Davidson II") when the Court held that "misled consumers may properly allege a threat of imminent or actual harm sufficient to confer standing to seek injunctive relief[.]" Plaintiffs are unable to rely on any future FDA attestations of safety and effectiveness. Defendants have injured Plaintiffs by permanently stripping them of any confidence in the FDA's statements and authorization and approval process.

Without FDA's action at issue here, none of the presented injury would have occurred, and Plaintiffs would not be under current threat. The injury Plaintiffs and their children sustained stems directly from FDA's unjustified authorization and the false representation that this biologic is a "vaccine" that has been adequately tested for safety. If this Court were to grant the relief

Plaintiffs seek, the "risk would necessarily be eliminated" and would protect not only Plaintiffs and their children, but all current and future children between the ages of 6 months and 11 years from FDA's arbitrary and capricious action. *Cutler v. Kennedy*, 475 F. Supp. 838, 850 (D.D.C. 1979), *disapproved of by Chaney v. Heckler*, 718 F.2d 1174 (D.C. Cir. 1983).

## V. SOVEREIGN IMMUNITY DOES NOT PREVENT THIS CHALLENGE

FDA claims immunity from suit. The FDA treats emergency power as a Pandora's Box of powers it can use to escape judicial review. The FDA goes further: the FDA claims it can unilaterally declare when it can open Pandora's Box and whether any action it takes comes from Pandora's Box. Thus, the FDA claims its false labeling of a biologic is magically an emergency power. But it isn't. The FDA claims its ability to open Pandora's Box is equally beyond judicial reach. But it isn't. This case challenges the FDA's mislabeling and prerogative to open Pandora's Box in the first place, neither of which is beyond judicial reach.

The FDA does not enjoy sovereign immunity, nor are Plaintiffs' causes of action beyond the APA's scope of review. MTD, p. 1. A waiver of sovereign immunity is "unequivocally expressed" in the APA. *Lane v. Pena*, 518 U.S. 187, 192, 116 S. Ct. 2092, 135 L.Ed.2d 486 (1996). 5 U.S.C. § 702 presents two requirements for establishing a waiver of sovereign immunity: (1) the plaintiff must "identify some 'agency action' affecting him in a specific way, which is the basis of his entitlement for judicial review," *Alabama-Coushatta Tribe of Texas, v. United States*, 757 F.3d 484 (5th Cir. 2014) (quoting 5 U.S.C. § 702), and (2) the plaintiff must demonstrate that she has "suffered legal wrong because of the challenged agency action, or is adversely affected or aggrieved by that action within the meaning of a relevant statute." *Lujan*, 497 U.S. at 883. "[W]here the Plaintiff is not seeking money damages, the APA acts as a waiver

of the government's sovereign immunity, allowing the plaintiff to proceed in federal court to rectify agency action." *Valerio v. Limon,* 533 F. Supp. 3d 439, 450 (S.D. Tex. 2021).

Exemptions from judicial review are rare and "not generally to be 'liberally construed.'" *United States v. Nordic Vill. Inc*., 503 U.S. 30, 34, 112 S. Ct. 1011, 117 L. Ed. 2d 181 (1992). There is a "'strong presumption' that Congress intends that the federal courts review agency action." *Lundeen v. Mineta,* 291 F.3d 300, 305 (5th Cir. 2002). Although 21 U.S.C. § 360bbb-3 does give discretion to the Agency and the Secretary of Health and Human Services, this discretion is not without bounds. The 5 U.S.C. § 701(a)(2) exception to sovereign immunity for action delegated to agency discretion is read "quite narrowly, restricting it to 'those rare circumstances where the relevant statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion.'" *Weyerhaeuser Co. v. United States Fish and Wildlife Serv*., 139 S.Ct. 361, 370, 202 L.Ed.2d 269 (2018) (quoting *Lincoln v. Vigil,* 508 U.S. 182, 191, 113 S.Ct. 2024, 124 L.Ed.2d 101 (1993)). FDA authorizations and approvals are not actions that are "traditionally committed to agency discretion." *Dep't of Com. v. New York,* 139 S. Ct. 2551, 2568, 204 L. Ed. 2d 978 (2019).

In any event, "nothing in the subsequent enactment of the APA altered the [pre-existing] doctrine of review." *Chamber of Commerce of the United States v. Reich,* 74 F.3d 1322, 1328 (D.C. Cir. 1996); see *Duncan v. Muzyn,* 833 F.3d 567, 578 (6th Cir. 2016) (recognizing the ongoing vitality of pre-APA review). As Prof. Davis put it shortly after the APA's enactment, when review is cut off under the Act (i.e., the APA), "[t]he result is that the pre-Act law continues." Kenneth Culp Davis, Nonreviewable Administrative Action, 96 U. PA. L.REV. 749, 776 (1948). Under that pre-APA review, "if an official acts solely on grounds which misapprehend the legal rights of the parties, an otherwise unreviewable discretion may become

subject to correction." *Arenas v. United States*, 322 U.S. 419, 432 (1944). The FDA, acting as a government agency, cannot evade responsibility for arbitrary and capricious actions under the APA, especially considering the perilous nature of authorizing biologics for children that skip traditional safety protocols. Holding that the FDA is immune from accountability here would deny citizens any proper recourse for addressing such unlawful operations.

## VI. PLAINTIFFS STATE COGNIZABLE CLAIMS ON WHICH THIS COURT CAN GRANT RELIEF

The FDA claims to be above the law. It is not.

### A. Plaintiffs' Challenge to the EUA is Reviewable

The APA expressly authorizes standing for citizens who are harmed by an agency's unlawful activity: "a person suffering legal wrong because of agency action…is entitled to judicial review thereof." 5 U.S.C. § 702. Indeed, the entire point of the APA was to assure judicial review of agency action, specifically authorizing federal courts to "hold unlawful and set aside agency action . . . found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; contrary to constitutional right, power, privilege, or immunity; [or] in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A)-(C).

### B. Plaintiffs Successfully Allege that Defendants Violated the APA

The APA affords Plaintiffs the right to challenge Defendants' conduct. The Supreme Court has indicated that a two-step procedure is required when examining an administrative exercise of discretion: first, a determination whether the agency has acted within the scope of its statutory authority, and second, whether the actual choice made was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971).

### i. Scope of Authority

CHD successfully pleaded that the FDA exceeded its statutory authority when mislabeling this biologic as a safe, effective vaccine for children ages 6 months through 11 years. "The reviewing court must also hold unlawful and set aside agency action that is contrary to constitutional right, in excess of statutory authority, or without observance of procedure required by law." *Monumental Task Comm., Inc. v. Foxx*, 157 F. Supp. 3d 573 (E.D. La. 2016), *aff'd sub nom. Monumental Task Comm., Inc. v. Chao*, 678 F. App'x 250 (5th Cir. 2017) (citing 5 U.S.C. § 706(2)(B)-(D)). The FDA does not contest that COVID-19 poses no "actual" or "potential" emergency for children in this age cohort; therefore, the emergency use statute, 21 U.S.C. § 360bbb-3(a)(1), does not authorize its action. FDA's actions exceeded its statutory authority, which this Court may review under both the APA and pre-APA review.

### ii. FDA's Arbitrary and Capricious Authorization

An agency's action is "arbitrary and capricious" if it did not articulate any rational connection between the facts it found and the choices it made. *Burlington Truck Lines v. United States*, 371 U.S. 156, 168, 83 S. Ct. 239, 9 L.Ed.2d 207 (1962). Plaintiffs successfully pleaded that the FDA's EUAs for children ages 6 months through 11 years fail to meet this standard. In its authorization, the FDA: (1) failed to examine relevant data; (2) failed to articulate its standard for assessment; (3) relied on factors not intended for it to consider; (4) failed to consider an important aspect of the problem; (5) offered an explanation that runs counter to the evidence; or (6) failed any aspect of reasoned decision-making in the process it utilized to come to its conclusions. *Motor Vehicle*, 463 U.S. at 43.

The FDA mislabeled Pfizer-BioNTech's biologic for children ages 6 months-11 years despite there being almost zero risk of serious injury or death from COVID-19. (Am. Compl. ¶

128). The FDA acted arbitrarily and capriciously by failing to engage in a pluralistic, critical, open, transparent and scientific dialogue with the public and medical community based on careful, deliberative evaluation of all relevant research before rushing this authorization. FDA's actions did not conform with reasoned decision-making, which requires detailing all the areas under 5 U.S.C. § 701. Unlike rational-basis review, review of agency action is based on the record before the agency. Compare *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto Ins. Co.*, 463 U.S. 29, 50 (1983) (APA); *SEC v. Chenery Corp.*, 318 U.S. 80, 88 (1943) (pre-APA) with *F.C.C. v. Beach Commc'ns, Inc.*, 508 U.S. 307, 315 (1993). The APA's requirement of "reasoned decision making" is offended since the FDA "agency action is lawful only if it rests 'on a consideration of the relevant factors.'" *Michigan v. E.P.A.*, 576 U.S. 743, 750 (2015) (citation omitted). As a result, plaintiffs state a cognizable claim for judicial review and remedy.

## CONCLUSION

Plaintiffs' First Amended Complaint properly asked this Court to vacate and remand the FDA's mislabeling of the Pfizer-BioNTech's COVID-19 vaccine for children 6 months through 11 years on the grounds that FDA's action was arbitrary and capricious, violated the APA, and exceeded the agency's statutory authority. Plaintiffs request that this Court prohibit the FDA from advertising and misrepresenting the biologic as "safe and effective" until the FDA has performed the proper analyses, as the law requires. The FDA's action cost substantial CHD resources, created health uncertainty for millions of children, and inflicted real risk of ongoing harm to Plaintiffs. This case is precisely what the Constitution intends when it empowers judicial review of a "case or controversy." Millions of lives depend on this Court's review. For the foregoing reasons, this Court should deny Defendants' Motion to Dismiss.

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Respectfully submitted,

/s/ Robert E. Barnes

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